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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/846,673	05/01/2001	Michael R. Dupelle	04644-088001	4557

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EXAMINER
BRADFORD, RODERICK D

ART UNIT	PAPER NUMBER
3762	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/846,673	Applicant(s) DUPELLE ET AL.	
	Examiner Roderick Bradford	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 May 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) *1-14 and 36-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8, drawn an external defibrillator, classified in class 607, subclass 5.

II. Claims 9-12, drawn to a medical device, classified in class 607, subclass 6.

III. Claims 13 and 14, drawn to a medical device, classified in class 607, subclass 149.

IV. Claims 15-35, drawn to a method of treating a patient showing signs of cardiac arrest, classified in class 607, subclass 4.

V. Claims 36-38, drawn to a method of treating a patient showing signs of cardiac arrest, classified in class 607, subclass 2.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require a strap for the pulse sensor. The

subcombination has separate utility such as not requiring defibrillator electrodes, but rather having sensors to sense physiological parameters.

3. Inventions I and III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require a foam pad for the pulse sensor. The subcombination has separate utility such as not requiring defibrillator electrodes, but rather having sensors to sense physiological parameters.

4. Inventions II and III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require a foam pad. The subcombination has separate utility such as not requiring a strap for the pulse sensor, but rather having the pulse sensor directly applied to the patient.

5. Inventions IV and V are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention IV

has separate utility such as not requiring the pulse sensor to determine whether to perform CPR on the patient. See MPEP § 806.05(d).

6. Inventions IV and V (process) and I, II and III (apparatus) are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used to practice another materially different process such as not requiring treating a patient showing signs of cardiac arrest, but rather treating atrial defibrillation.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

8. During a telephone conversation with Roger Lee on February 11, 2003 a provisional election was made with traverse to prosecute the invention of Group IV, claims 15-35. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-14 and 36-38 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 15-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Referring to claims 15 and 35, "a method of treating" is vague because the preamble is inconsistent with the claim body and the claim is incomplete since there is no step for "treating a patient".

Claims 27, 29 and 30-34 are vague because they are in the past tense and method claims need actively recite method steps.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

12. Claims 15-19, 21-24, 29, 32, 34 and 35 are rejected under 35 U.S.C. 102(e) as being anticipated by Joo et al. U.S. Patent. No. 6,440,082.

Referring to claims 15 and 35, Joo discloses a method for treating possible cardiac arrest comprising:

- applying a piezoelectric pulse sensor to the patient (Fig. 2 and column 4, lines 60, 61)
- applying electrodes of a defibrillator to the patient (Fig. 2)
- using the pulse sensor to detect whether the patient has a pulse (Fig. 4 and column 6, lines 45-52).

Referring to claim 16, further comprising monitoring the pulse if present (column 13, lines 53-65).

Referring to claim 17, wherein the defibrillator has an ECG function and the method further comprises using the ECG of the defibrillator to monitor the patient's heart rhythm (column 5, lines 51-53).

Referring to claim 18, further comprising analyzing the pulse and heart rhythm to determine the appropriate treatment for the patient (Fig. 11).

Referring to claim 19, wherein the analyzing step includes determining whether the patient's pulse, if present, is correlated with the R-wave of the patient's heart rhythm (column 3, lines 1-7 and column 8, lines 31-36).

Referring to claims 21 and 22, wherein the analyzing step includes determining whether the ECG rhythm is treatable with defibrillation and delivering a shock to the patient using the defibrillator (column 12, lines 22-27 and column13, lines 3-5).

Referring to claim 23, further comprising delivering a predetermined number of shocks to the patient, and then subsequently determining whether the patient's pulse, is correlated with the R-wave (column 13, lines 18-21).

Referring to claim 24, further comprising, if the subsequent determination is negative, administering CPR (column 13, lines 21-25).

Referring to claim 29, wherein the pulse sensor is mounted on one of the electrodes of the defibrillator (column 4, lines 53-55).

Referring to claim 34, wherein the pulse sensor is attached to pulse point other than the patient's neck (Fig. 2).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of

35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 20, 25, 26, 27, 28, 30, 31 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Joo et al. U.S. Patent No. 6,440,082.

Referring to claims 20 and 25, Joo discloses the claimed invention except for wherein the determination is positive, no ECG analysis is performed and further comprising using a pulse sensor to determine the efficacy of the CPR treatment.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as taught by Joo, with if the determination is positive that no ECG analysis is performed and comprising a pulse sensor to determine the efficacy of the CPR treatment since it was well known in the art that if the determination is positive then no ECG analysis will be performed as a means not to waste battery life performing unnecessary ECGs and having pulse sensors to determine the efficacy of treatment as a means to determine if the patient will need further care.

Referring to claims 26 and 31, Joo discloses the claimed invention except for wherein the pulse sensor comprises a piezoelectric polymer film and is self-shielded.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as taught by Joo, with wherein the pulse sensor that comprises a piezoelectric polymer film and are self-

shielded since it was well known in the art to use a piezoelectric polymer film and self-shielding pulse sensors as a means to reduce interference.

Referring to claims 27, 28, 30 and 33, Joo discloses the claimed invention except for wherein the pulse sensor is mounted on an elastic strap and further attaching the elastic strap around the patient's neck and wherein the pulse sensor further comprises a foam layer.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as taught by Joo, with a pulse sensor mounted on an elastic strap and further attaching the elastic strap around the patient's neck and where the pulse sensor further comprises a foam layer since it was well known in the art to include a pulse sensor mounted on an elastic strap and further comprising attaching the elastic strap around the patient's neck and where the pulse sensor further comprises a foam layer as an alternate means for monitor the pulse of a patient and to provide the elastic strap so the sensor can comfortably fit and be used on different patients.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roderick Bradford whose telephone number is (703) 305-3287. The examiner can normally be reached on Monday - Friday 7 a.m. - 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone numbers for the organization where this application or proceeding is

assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

R. Bradford
R.B. 2/24/03
February 24, 2003

GEORGE R. EVANISKO
PRIMARY EXAMINER
2/24/03